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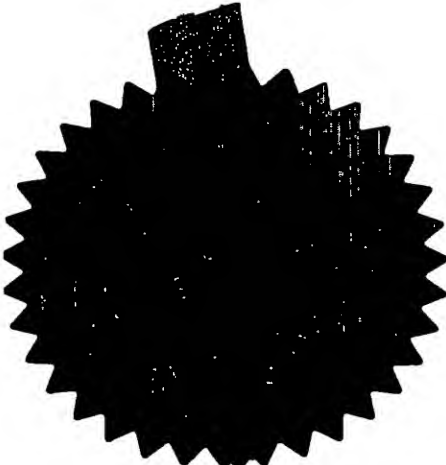
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L. Mahoney

Signed

Dated 25 November 2003

Request for grant of a patent

1/77

The Patent Office

Cardiff Road
Newport
Gwent NP9 1RH



1. Your reference

SH/42371

2. Patent application number

0225502.4

3. Full name, address and post code of the or each applicant

Zoolife International Limited
55 Elizabeth Street
London
SW1W 9PP

Patents ADP number

If the applicant is a corporate body, give the country/state of its incorporation

United Kingdom

8445181001

4. Title of the invention

THERAPEUTIC AND PROPHYLACTIC PREPARATIONS

5. Name of your agent

VENNER, SHIPLEY & CO

"Address for service" in the United Kingdom to which all correspondence should be sent

20 LITTLE BRITAIN
LONDON
EC1A 7DH

Patents ADP

1669004

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or each of these earlier applications and the or each application number

Country

Priority application number

Date of filing

7. If this application is divided or otherwise derived from an earlier UK application, give the number and filing date of the earlier application

Number of earlier application

Date of Filing

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? (Answer 'YES' if:

YES

- a) any applicant in 3. above is not an inventor, or
- b) there is an inventor who is not named as an applicant, or
- c) any named applicant is a corporate body)

Patents Form 1/77

9. Enter the number of sheets for any of the following items you are filing with this form.
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Continuation sheets of this form

Description 3

Claim(s) 1

Abstract 1

Drawing(s)

10. If you are also filing any of the following state how many against each item.

Priority documents

Translations of priority documents

Statement of inventorship and right to grant of a patent (*Patents Form 7/77*)

Request for preliminary examination and search (*Patents Form 9/77*)

Request for substantive examination (*Patents Form 10/77*)

Any other documents

11.

I/We request the grant of a patent on the basis of this application.

Signature

Date

1 November 2002

Kenner, Shiple & Co.

12. Name and daytime telephone number of person to contact in the United Kingdom

SIAN HUGHES
020 7600 4212

Therapeutic and Prophylactic Preparations

The present invention relates to preparations for the treatment or prevention of clinical conditions in animals and, in particular in aquatic animals.

5

The management of clinical conditions for animals, particularly the management of clinical conditions in fish, invertebrates and amphibians is very important, both in terms of animal well-being and in commercial terms where the animals are sold or displayed and clearly need to be in good health.

10

However, the treatment or prophylaxis of clinical conditions such as inflammation in animals can often be problematic and it is desirable to keep the disturbance to the animals to a minimum.

15

According to the present invention, a preparation comprising 1,3/1,6 beta glucans is provided, for use in the treatment or prevention of infection, inflammation, and/or traumatic conditions.

20

1,3/1,6 beta glucans are commercially available under the name MacroGard® from Biotec ASA (Tromsø, Norway). The 1,3/1,6 beta glucans are derived from Baker's yeast (*Saccharomyces cerevisiae*).

25

In a preferred embodiment, the preparation further comprises vitamins, minerals, carotenoids, amino acids, lipids, peptides, nucleotides, bioflavonoids, oils and/or polysaccharides. The inclusion of vitamins such as Vitamin C, particularly as ascorbyl polyphosphate, is especially effective where the formulation is used to treat fish.

30

It has previously been disclosed that 1,3/1,6 beta glucans have immunostimulatory properties when administered to fish. It has now been discovered that 1,3/1,6 beta glucans are highly beneficial in the management of infective, traumatic and inflammatory conditions in animals such as fish. They are also useful in the management of skin and fin conditions in fish. It has further been discovered that

the 1,3/1,6 beta glucans improve food utilisation and so are particularly useful in farming and breeding of ornamental fish

5 The preparation according to the invention may be used in bath or immersion treatment, or can be administered orally or by injection.

Bath or immersion treatment has been found to be effective in the management of clinical conditions for animals, particularly for the management of clinical conditions in fish, invertebrates and amphibians. The preparation according to the present invention may be administered as a short term bath or immersion treatment, or may be added to water systems containing animals for longer term applications.

15 The beta glucans used in a preparation for bath or immersion treatment are preferably soluble. Soluble 1,3/1,6 beta glucans are commercially available under the name MacroGard® AquaSol from Biotec ASA (Tromsø, Norway). The 1,3/1,6 glucans are derived from Baker's yeast (*Saccharomyces cerevisiae*) and are made soluble by a patent process.

20 The soluble 1,3/1,6 beta glucans are added to the water, for example in an amount of 1ml per litre of water, for treatment of fish over a period of 1-24 hours. When used in this way, the preparation according to the present invention has been shown to produce a marked increase in the rate of wound healing and reduces associated inflammation.

25 Use of the preparation according to the present invention as a bath additive has also been shown to have a beneficial effect on improving mucus quality in fish.

30 Bath or immersion treatment clearly has the advantage that a number of animals may be treated together rather than requiring individual attention. What is more, the animals may not even be aware that they are being treated. The preparation according to the present invention has been used as a bath treatment for a very wide range of marine and fresh water fish and has been found to have excellent safety during and following application.

When the preparation of the present invention is to be administered by injection, this may be by subcutaneous, intramuscular or intravenous injection.

5 Pure 1,3/1,6 beta glucans have been administered by injection in an amount of 0.01-0.2mls per 100g bodyweight for the management of inflammatory and/or infective conditions in fish. Such administration has shown a marked increase in the rate of wound resolution, reducing the effects of toxins and appearing to have a marked anti-inflammatory effect. The effects of treatment have been very noticeable in
10 cases of bacterial infections, particularly with *Vibrio* species and most noticeably with *Vibrio vulnificus* (which is known to produce exotoxins).

When the preparation according to the invention is intended for administration by injection, it is preferable to use soluble 1,3/1,6 beta glucans.

15

The preparation according to the present invention may also be administered orally. The 1,3/1,6 beta glucans may be either in the soluble or non-soluble form. The preparation may be formulated into liquid or solid form. Particularly preferable are tablets, (hard or soft shell) capsules, liquids and powders. The preparation may be
20 added to the animal feed, for example by injection or pressure treatment of feed, or simply by sprinkling the powder or liquid form onto feed.

In order to increase the shelf life of the formulation according to the present invention, the formulation may include conventional preservatives.

25

In a preferred embodiment, the preparation according to the present invention includes an excipient and preferably a pharmaceutically acceptable excipient.

The formulations according to the present invention have been found to be
30 particularly useful in preventing deterioration of the clinical condition of fish, including ornamental and farmed fish, as a result of their transportation. The preparation is simply administered in one of the ways described above prior to transportation of the fish.

Claims

1. A preparation comprising 1,3/1,6 beta glucans, for use in the treatment or prevention of infection, inflammation, and/or traumatic conditions in an animal.

5

2. A preparation as claimed in claim 1, wherein the animal is a fish.

3. A preparation as claimed in either of claims 1 and 2, wherein the preparation further comprises vitamins, minerals, carotenoids, amino acids, lipids, peptides,
10 nucleotides, bioflavinoids, oils and/or polysaccharides.

4. A preparation as claimed in claim 3, wherein the preparation further comprises Vitamin C, preferably as ascorbyl polyphosphate.

15 5. A preparation as claimed in any one of the preceding claims, wherein the preparation is for administration by injection.

6. A preparation as claimed in any one of claims 1-4, wherein the preparation is for use in bath or water immersion treatment.

20

7. A preparation as claimed in any one of claims 1-4, wherein the preparation is for oral administration.

8. A preparation as claimed in claim 7, wherein the preparation is in the form
25 of a powder, liquid, tablet or capsule.

Abstract

Therapeutic and Prophylactic Preparations

- 5 The present invention provides a preparation comprising 1,3/1,6 beta glucans, for use in the treatment or prevention of infection, inflammation, and/or traumatic conditions. The preparation may be used in bath or immersion treatment, or can be administered orally or by injection.